Docket Number: ENP-030

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Or et al. Art Unit : 1653
Serial No. : 09/976,219 Examiner : Samuel W. Liu
Filed : October 12, 2001
Title : Cyclosporins for the Treatment of Respiratory Diseases

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO NON-FINAL OFFICE ACTION

Applicants respectfully request the entry of the following amendments [a total of 7 pages] to the instant patent application, in response to the Office Action mailed July 16, 2003 (the "Action") and the telephonic interview conducted with Examiners Liu and Carlson on November 6, 2003 (the "Interview").

Pages 2-5 present a claim listing.

Pages 6-7 contain remarks.

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Mail Stop Non-Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or being facsimile transmitted to the USPTO, on the date indicated below.

11/17/2003
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Signature

Jason D. Ferrone (Reg. No. 52,887)
Typed or Printed Name of Person Signing Certificate

AMENDMENTS TO THE CLAIMS: THIS LISTING OF CLAIMS REPLACES ALL PRIOR VERSIONS AND THOSE CLAIMS LISTED IN THE APPLICATION AS FILED.

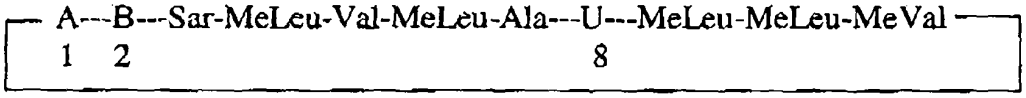
Claims 1-4 (Cancelled)

Claims 5-10 (Withdrawn)

Claim 11 (Cancelled)

Claims 12-14 (Withdrawn)

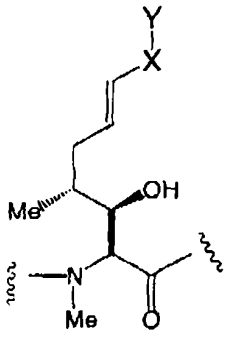
15. (Currently Amended) A cyclosporin analog of formula I or a pro-drug or a pharmaceutically acceptable salt thereof:



(I)

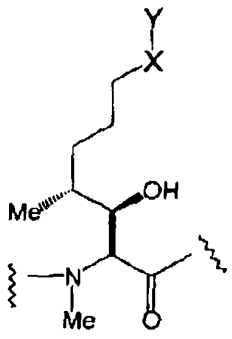
wherein

(i) A is of the formula:



(A1)

or



(A2)

wherein:

X is absent, -C1-C6 alkyl-, or -C3-C6 cycloalkyl-;

Y is selected from the group consisting of:

(a) aryl substituted with one or more substituents independently selected from: CN, ~~C_1-C_3-alkyl~~, C_3-C_6-alkoxy, C_1-C_6-alkoxy, C_3-C_6-alkoxy substituted with aryl, haloalkyl, thioalkoxy, amino, alkylamino, mercapto, nitro, carboxaldehyde, carboxy, alkoxycarbonyl, or carboxamide;

(b) heteroaryl; or

(c) substituted heteroaryl;

(ii) B is -αAbu-, -Val-, -Thr- or -Nva-; and

(iii) U is -(D)Ala-, -(D)Ser-, -[O-(2-hydroxyethyl)(D)Ser]-, -[O-(acyl)(D)Ser]- or -[O-(2-acyloxyethyl)(D)Ser]-.

16. (Currently Amended) A cyclosporin analog of claim 15 defined by formula I, wherein X is absent and Y is phenyl substituted at the ortho position with a substituent independently selected from: CN, ~~C_1-C_3-alkyl~~, C_3-C_6-alkoxy, C_1-C_6-alkoxy, C_3-C_6-alkoxy substituted with aryl, haloalkyl, thioalkoxy, amino, alkylamino, mercapto, nitro, carboxaldehyde, carboxy, alkoxycarbonyl, or carboxamide.

17. (Currently Amended) A cyclosporin analog according to claim 15 or a pro-drug or a pharmaceutically acceptable salt thereof, selected from the group consisting of:

~~Compound of formula (I), where A=A1, X is absent and Y = (2'-Me)Ph; B is –αAbu-; and U is –(D)Ala-;~~

Compound of formula (I), where A=A1, X is absent and Y = (4'-CF_3)Ph; B is –αAbu-; and U is –(D)Ala-;

Compound of formula (I), where A=A1, X is absent and Y = (2'-OMe)Ph; B is –αAbu-; and U is –(D)Ala-;

Compound of formula (I), where A=A1, X is absent and Y = (3'-$COOCH_3$)Ph; B is –αAbu-; and U is –(D)Ala-;

Compound of formula (I), where A=A1, X is absent and Y = (4'-$COOCH_3$)Ph; B is –αAbu-; and U is –(D)Ala-;

Compound of formula (I), where A=A1, X is absent and Y = (2'- Naphthalene); B is –αAbu-; and U is –(D)Ala-;

Compound of formula (I), where A=A1, X is absent and Y = (4'-t-butyl)Ph; B is –αAbu-; and U is –(D)Ala-;

Compound of formula (I), where A=A1, X is absent and Y = (4'-AcO-)Ph; B is –αAbu-; and U is –(D)Ala-;

Compound of formula (I), where A=A1, X is absent and Y = (4'-OCH_3)Ph; B is –αAbu-; and U is –(D)Ala-;

Compound of formula (I), where A=A1, X is absent and Y = (3', 4'-OMe_2)Ph; B is –αAbu-; and U is –(D)Ala-;

~~Compound of formula (I), where A=A1, X is absent and Y = (2',5'-Me_2)Ph; B is –αAbu-; and U is –(D)Ala-;~~

Compound of formula (I), where A=A1, X is absent and Y = Pyridine; B is –αAbu; and U is –(D)Ala-;

Compound of formula (I), where A=A1, X is absent and Y = Pyrrole; B is –αAbu; and U is –(D)Ala-;

Compound of formula (I), where A=A1, X is absent and Y = (N-methyl) Pyrrole; B is –αAbu; and U is –(D)Ala-;

Compound of formula (I), where A=A1, X is absent and Y = Thiophene; B is –αAbu; and U is –(D)Ala-;

Compound of formula (I), where A=A1, X is absent and Y = Oxazole; B is –αAbu; and U is –(D)Ala-;

~~Compound of formula (I), where A=A2, X is absent and Y = (2'-Me)Ph; B is –αAbu; and U is –(D)Ala-;~~

Compound of formula (I), where A=A1, X is absent and Y = (S)Ph; B is –αAbu; and U is –(D)Ala-;

Compound of formula (I), where A=A1, X is absent and Y = (SO)Ph; B is –αAbu; and U is –(D)Ala-; and

Compound of formula (I), where A=A1, X is absent and Y = (SO_2)Ph; B is –αAbu; and U is –(D)Ala-.

Claim 18 (Cancelled)

19. (Previously Presented) A pharmaceutical composition, said composition comprising at least one cyclosporin analog of formula I as claimed in Claim 15, said cyclosporin analog being present alone or in combination with a pharmaceutically acceptable carrier or excipient.

20. (New) A compound according to claim 15, wherein X is absent and Y is substituted heteroaryl.

21. (New) A compound according to claim 15, wherein X is absent and Y is (2'-methyl)furan-2-yl.

REMARKS

Applicants would like to express their gratitude to Examiners Liu and Carlson for granting a telephonic interview for the instant patent application. Claims 15-17 and 19-21 remain pending in the instant patent application upon the entry of the amendments presented herewith. Applicants have cancelled claims 1-4, 11, and 18, amended claims 15-17, and presented new claims 20 and 21 in the instant response. Applicants make such amendments without prejudice to pursuing the originally presented or cancelled subject matter in a later application claiming benefit of this application, and particularly without prejudice to determination of equivalents of subject matter of this application or any later application claiming benefit of this application. No new matter has been added. Amendments to claims 15 and 16 find support in the paragraph beginning at line 4 on page 14 of the specification as originally filed. Newly presented claims find support in the claims as originally filed and in the paragraph beginning at line 22 at page 14 of the specification as originally filed.

Rejection Under 35 U.S.C. §102(b)

Applicants presented amendments to claims 15-17 in accordance with the interview conducted with Examiners Liu and Carlson. Applicants submit that the claim rejections no longer are applicable to the pending claims. Thus, Applicants respectfully request that the rejection be reconsidered and withdrawn.

Rejection Under 35 U.S.C. §103(a)

Applicants have presented amendments to claims 15-17 in accordance with the interview conducted with Examiners Liu and Carlson. Applicants submit that the claim rejections no longer are applicable to the pending claims. Thus, Applicants respectfully request that the rejection be reconsidered and withdrawn.

Provisional Rejection - Obviousness-Type Double Patenting

Applicants submit that Terminal Disclaimers have been filed over application serial numbers 09/800,856 and 09/975,923. Therefore, Applicants respectfully request that the rejection be reconsidered and withdrawn.

Docket Number: ENP-030
Response to July 16, 2003 Action

Applicant : Or et al.
Serial No. : 09/976,219
Filed : October 12, 2001
Title : Page 7 of 7

Upon the allowance of the pending claims, Applicants respectfully request the rejoinder of the withdrawn method claims 12-14 to the instant application.

Applicants submit that the claims are in condition for allowance. Please charge the fee for a one month extension of time under 37 C.F.R. § 1.17 (a) (1) along with any other deficiencies to Enanta Pharmaceuticals, Inc., Deposit Account No. 50-2010, referencing Attorney Docket No. ENP-030.

Respectfully submitted,

Date: Nov. 17, 2003

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